

A circular stamp from the Office of Intellectual Property (OIP). The text "OIP" is at the top, "INF" is on the right, "MAR 10 2003" is in the center, and "PATENT & TRADEMARK OFFICE" is at the bottom.



BEST AVAILABLE COPY

RECEIVED  
Sheet 1 of 1  
MAR 11 2003  
TECH CENTER 1600/2900Form PTO-1449  
(Rev. 8-88)U.S. Department of Commerce  
Patent and Trademark Office

Attorney Docket No.

C-3407/1/US

Applicant

Gao et al.

Filing Date

January 15, 2002

Serial No.

10/047,272

Group No.

1614

INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

## OTHER DOCUMENTS (Including author, title, date, pertinent pages, etc.)

|     |   |
|-----|---|
| MP4 | Fujioka & Tan, Biopharmaceutical Studies on Hydantoin Derivatives. III. Physico-Chemical Properties, Dissolution Behavior, and Bioavailability of the Molecular Compound of 1-Benzenesulfonyl-5,5-Diphenylhydantoin and Antipyrine, <i>J. Pharm. Dyn.</i> , 5, pp. 475-484, (1982). |
|     | Fujii et al., Dissolution and Bioavailability of Phenobarbital in Solid Dispersion with Phosphatidylcholine, <i>Chem. Pharm. Bull.</i> , Vol. 39., pp. 1886-1888, (1991).   |
|     | Higuchi, Physical Chemical Analysis of Percutaneous Absorption Process From Creams and Ointments, <i>Journal of the Society of Cosmetic Chemists</i> , 11, pp. 85-97, (1959).   |
|     | Higuchi & Farvar, Drug Membrane Transport Enhancement Using High Energy Drug-Povidone Coprecipitates, <i>Proc. Int. Symp.</i> , pp. 71-79, (1993).  |
|     | Iervolino et al., Penetration enhancement of ibuprofen from supersaturated solutions through human skin, <i>International Journal of Pharmaceutics</i> , 212, pp. 131-141, (2001).  |
|     | Kondo et al., Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug, <i>Journal of Pharmaceutical Sciences</i> , Vol. 83, No. 4, pp. 566-570, (1994).   |
|     | Kohri et al., Improving the Oral Bioavailability of Albendazole in Rabbits by the Solid Dispersion Technique, <i>J. Pharm. Pharmacol.</i> , 51, pp. 159-164, (1999).  |
|     | Ledwidge & Corrigan, Effects of surface active characteristics and solid state forms on the pH solubility profiles of drug-salt systems, <i>International Journal of Pharmaceutics</i> , 174, pp. 187-200, (1998).  |
|     | Loftsson & Sigurðardóttir, The effect of polyvinylpyrrolidone and hydroxypropyl methylcellulose on HPBCD complexation of hydrocortisone and its permeability through hairless mouse skin, <i>European Journal of Pharmaceutical Sciences</i> , 2, pp. 297-301, (1994).              |
|     | Loftsson et al., The effect of water-soluble polymers on aqueous solubility of drugs, <i>International Journal of Pharmaceutics</i> , 127, pp. 293-296, (1996).   |
|     | Megrab et al., Oestradiol permeation through human skin and silastic membrane: effects of propylene glycol and supersaturation, <i>Journal of Controlled Release</i> , 36, pp. 277-294, (1995).   |
|     | Moser et al., Stabilization of supersaturated solutions of a lipophilic drug for dermal delivery, <i>International Journal of Pharmaceutics</i> , 224, pp. 169-176, (2001).   |
|     | O'Driscoll & Corrigan, Chlorothiazide-Polyvinylpyrrolidone (PVP) Interactions: Influence on Membrane Permeation (Everted Rat Intestine) and Dissolution, <i>Drug Development and Industrial Pharmacy</i> , 8(4), pp. 547-564, (1982).   |
|     | Raghavan et al., Effect of cellulose polymers on supersaturation and in vitro membrane transport of hydrocortisone acetate, <i>International Journal of Pharmaceutics</i> , 193, pp. 231-237, (2000).   |
|     | Raghavan et al., Crystallization of hydrocortisone acetate: influence of polymers, <i>International Journal of Pharmaceutics</i> , 212, pp. 213-231, (2001).  |
|     | Raghavan et al., Membrane transport of hydrocortisone acetate from supersaturated solutions; the role of polymers, <i>International Journal of Pharmaceutics</i> , 221, pp. 95-105, (2001).   |
|     | Serajuddin & Jarowski, Influence of pH on Release of Phenytoin Sodium from Slow-Release Dosage Forms, <i>Journal of Pharmaceutical Sciences</i> , Vol. 82, No. 3, pp. 306-310, (1993).  |
| MP4 | Simonelli et al., Inhibition of Sulfathiazole Crystal Growth by Polyvinylpyrrolidone, <i>Journal of Pharmaceutical Sciences</i> , Vol. 59, No. 5, pp. 633-638, (1970).  |

Examiner

Muth Pullen

Date Considered

9/23/03

\*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP §609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

|   |  |   |  |  |  |                            |  |
|---|--|---|--|--|--|----------------------------|--|
| Form PTO-1449<br>(Rev. 8-88)  |  | U.S. Department of Commerce<br>Patent and Trademark Office  |  | Attorney Docket No.<br><br>C-3407/1/US |  | Serial No.<br>10/047,222-1 |  |
| <b>INFORMATION DISCLOSURE STATEMENT</b><br>(Use several sheets if necessary)  |  |   |  | Applicant<br><br>Gao et al.            |  | Group No.                  |  |
|   |  |   |  | Filing Date<br><br>January 15, 2002    |  | 1614                       |  |
|   |  |   |  |  |  |                            |  |
| <b>OTHER DOCUMENTS</b> (Including author, title, date, pertinent pages, etc.)   |  |   |  |  |  |                            |  |
| mcy   |  | Simonelli et al., Dissolution Rates of High Energy Sulfathiazole-Povidone Coprecipitates II: Characterization of Form of Drug Controlling Its Dissolution Rate via Solubility Studies, <i>Journal of Pharmaceutical Sciences</i> , Vol. 65, No. 3, pp. 355-361, (1976). |  |  |  |                            |  |
| ↑   |  | Suzuki & Sunada, Comparison of Nicotinamide, Ethylurea and Polyethylene Glycol as Carriers for Nifedipine Solid Dispersion Systems, <i>Chem. Pharm. Bull.</i> , 45(10), pp. 1688-1693, (1997).  |  |  |  |                            |  |
|   |  | Suzuki & Sunada, Some Factors Influencing the Dissolution of Solid Dispersions with Nicotinamide and Hydroxypropylmethylcellulose as Combined Carriers, <i>Chem. Pharm. Bull.</i> , 46(6) pp. 1015-1020, (1998).  |  |  |  |                            |  |
|   |  | Yamada et al., Effect of Grinding with Hydroxypropyl Cellulose on the Dissolution and Particle Size of a Poorly Water-Soluble Drug, <i>Chem. Pharm. Bull.</i> , 47(9), pp. 1311-1313, (1999).   |  |  |  |                            |  |
| ↓   |  | Yamamoto et al., Dissolution Behavior and Bioavailability of Phenytoin from a Ground Mixture with Microcrystalline Cellulose, <i>Journal of Pharmaceutical Sciences</i> , Vol. 65, No. 10, pp. 1484-1488, (1976).   |  |  |  |                            |  |
| Examiner<br><br>Michael Paul Jones  |  |   |  | Date Considered<br><br>9/23/03         |  |                            |  |
| *Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP §609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |  |   |  |  |  |                            |  |

BEST AVAILABLE COPY